

**REMARKS**

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

**I. Claim Status and Amendments**

Claims 1-11 were pending in this application when last examined and stand rejected.

Claims 2, 3, 6, 9, and 11 have been amended by way of the present amendment. Claims 2 and 3 are amended to independent form and to further specify the constituents of the compounds as supported by the specific compounds disclosed in Examples 1 to 6 of the specification. Claim 6 is amended to change dependency to claim 2. Claims 9 and 11 are amended to be consistent with the amendments to claims 2 and 3. Further support can be found throughout the general disclosure, see for example, page 3, line 12 to page 5, line 12, page 9, line 22, and page 10, lines 12-17, and the claims as originally filed. No new matter has been added.

Applicants have added new claims 12-14 that correspond to claims 6-8, respectively, but depend on claim 3. Further support can be found in the disclosure, for example, at page 12, lines 13-20. No new matter has been added.

Claims 1, 4, and 5 have been cancelled without prejudice or disclaimer thereto. Applicants reserve the right

to file a continuation or divisional application on any cancelled subject matter.

Claims 2, 3 and 6-14 are pending upon entry of this amendment, and these claims define patentable subject matter warranting their allowance for the reasons set forth herein.

## **II. Enablement Rejection Under 35 USC §112**

Claims 1-11 were rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification is enabled for salts or esters of the claimed compounds, but for not hydrates thereof for the reasons set forth in item 2 on pages 2-5 of the Office Action.

For the sole purpose of expediting prosecution and not to acquiesce to the rejection, Applicants have deleted the term "hydrates" from the claims, thereby obviating this rejection. Thus, withdrawal of the rejection is requested.

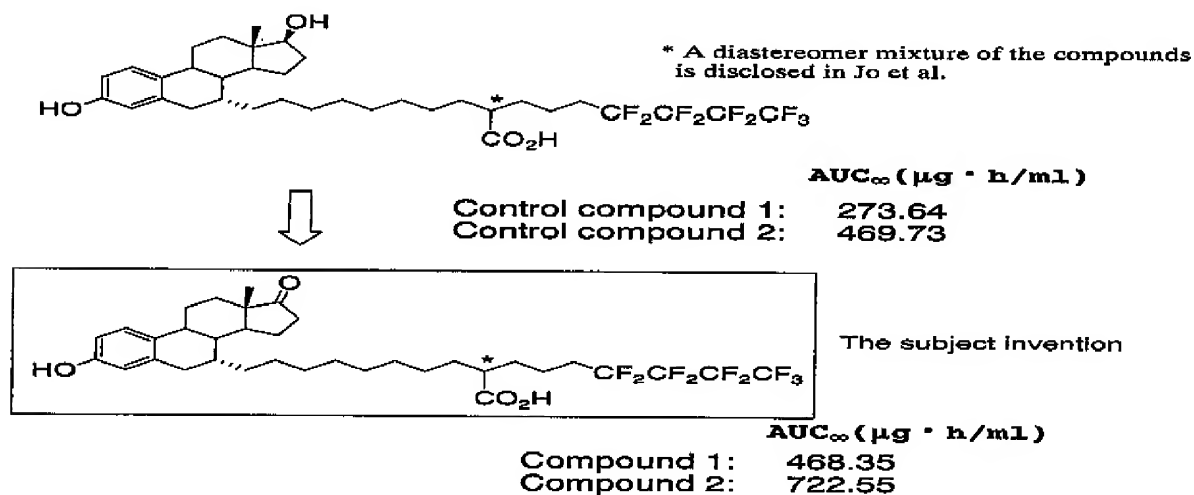
## **III. Obviousness Rejection Under 35 USC §103(a)**

Claims 1-11 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Jo et al. (WO 0142186, see English translation US 6,737,417) for the reasons in item 4 on pages 5-8 of the Office Action. In making the rejection, the Examiner relies on Jo et al. as allegedly disclosing compounds

relevant to the claims. This rejection is respectfully traversed as applied to the amended and new claims.

First, the rejection should fall, because Jo et al. fail to teach, suggest or make obvious all of the limitations, namely, the specific compounds of the amended and new claims, as required to support a *prima facie* case of obviousness.

The differences between the claimed compounds and those in Jo et al. and the advantageous effect of the claimed compounds are illustrated, by way of example, in the following figure, which is based on the results disclosed in Table 2.



Compounds 1 and 2 are optically active compounds of the claimed invention and were prepared in Example 2 (pages 19-20) of the subject specification from Control Compounds 1 and 2, respectively. Jo et al. do not disclose or suggest these compounds. Instead, Jo et al. disclose the diastereomer mixture of Control Compounds 1 and 2 in Example 15 (column 94

of US 6,737,417 B2). As can be seen, Control Compounds 1 and 2 differ in chemical structure from Compounds 1 and 2 of the claims.

Second, in addition to their structural differences, the claimed compounds exhibit different chemical properties from the compounds in Jo et al. The amended claims of the instant application are fully supported by the compounds disclosed in Examples 1 to 6 of the subject specification, and consequently the significant effect of the claimed compounds is clearly indicated by the assay results in Tables 2 to 5 of the subject specification. Compounds 1 and 2 have a much higher AUC value compared with Control Compounds 1 and 2, respectively.

Further, compounds 1 and 2 also have potent pharmacological efficacy in oral administration. The specification also discloses potent anti-estrogen activity and excellent pharmacokinetic property of Compounds 2 to 5 in Tables 2 to 5. Yet, Jo et al. do not include any teaching or suggestion indicating that the compounds disclosed therein have the same or similar properties, such as the excellent pharmacokinetic properties of the claimed compounds.

Moreover, it is believed that the above-noted results constitute unexpected results indicative of the non-obviousness of the claims, since they show that compounds of

the claims exhibit superior effects and properties over the compounds in Jo et al. as discussed above. It is well established that the presence of unexpectedly improved properties or properties not present in the prior art are indicative of non-obviousness. *Dillon*, 919 F.2d 688, 692-93, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990). See also M.P.E.P., Eighth Ed., Rev. 6 (September 2007) at § 716.02(a) I-IV and § 2145.

Thus, it is clear that the claimed compounds differ structurally and in chemical properties from the compounds in Jo et al., and it is believed that they exhibit unexpected and superior properties indicative of non-obviousness.

Third, the rejection should fall, because it would not have been predictive to modify the compounds of Jo et al. to arrive at the claimed compounds with a reasonable degree of success. As acknowledged by the Examiner at page 7 of the Office Action, Jo et al. do not disclose the specifically claimed compounds. Instead, Jo et al. disclose a diastereomer mixture of Control Compounds 1 and 2, as discussed above. Yet, on page 7 of the Action, the Examiner argues that the motivation to modify the prior art compounds would have been "on the desire to increase activity of the compounds after oral administration as taught by Jo et al." However, as shown above, the compounds of Jo et al. clearly differ structurally

and in their chemical properties from the claimed compounds. Further, it is known that diastereomers can and often do have different physical properties and different reactivity. Due to these differences in structure and chemical properties, it cannot be said that the compounds in Jo et al. are predictive of the claimed compounds.

Based on the above, it is clear that the compounds in Jo et al. are not the same as, nor are they suggestive of, the compounds of claims 2, 3, 9, and 11; and the claimed compounds achieve unexpectedly improved properties indicative of non-obviousness. For these reasons, the teachings of Jo et al. cannot render obvious the compounds of independent claims 2, 3, 9, and 11. Thus, these claims and all claims dependent thereon are believed to be novel and patentable over Jo et al. Withdrawal of the above 103(a) obviousness rejection is therefore solicited.

## **VI. Conclusion**

Having addressed all the outstanding issues, the amendment is believed to be fully responsive to the Office Action. It is respectfully submitted that the application is in condition for allowance and notice to that effect is hereby requested.

Appln. No. 10/509,377  
Response dated June 4, 2009  
Reply to Office Action of March 10, 2009

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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